

Appendix: 9

Pat Spitzig's Opening Remarks
FDA / CDRH / OSB Outside Leveraging Seminar
10/28/98

It's wonderful to have you all here.

Pervasiveness of OL:

As I worked on this project, that had no name (until I heard National Public Radio story), I became sensitized to the many examples of OL "Outside Leveraging"

I began to see the world differently.

- While filling my cup with lemonade, I realized
 - Fast Food restaurants
 - Gas stations
 - Banks / Money machines
 - Telephone (dialing our own ID numbers)
- are all examples of outside leveraging.

It's become...a normal way of doing business.

There are positive and negative aspects to this

- the product probably costs less
 - may save time & increase the volume of business
- but we may be charged to do the work (banks)
 - may be inconvenienced and loose time
 - e.g. lengthy voice mails

Some OL has been very innovative:

- Ralph Lauren is renovating the Besty Ross flag
- The Army Corps of Engineers is partnering with the D.C. Public School system
- Baltimore Police Commission projects where police -- helping inner city school children.

But in fact Last winter / spring --there was nothing in the literature

Not that it is not happening, but apparently -- busy people

- not writing,
- trying to get their work done, but they aren't documenting their experience

Then gratefully I found on the Internet

The National Performance Review Office

- put my request for information in their system and

This led us to the case studies that are the basis of today's seminar.

- The keynote speakers, panelists and other resources are the result.
- We continue to be interested in new examples as you see them in the literature.

We also want to be sure to acknowledge:

- when viewed with an OL lens -- we find some of our coworkers are doing work that is OL. This is the source of our panelists. But there is more:
 - our IMS group regularly gets outside input on the public health advisories and notices we send.
 - Our Division of Surveillance Systems has worked with the Center for Drugs on systems and with others outside the agency on nomenclature for making our Database available outside FDA.

But despite our desire to acknowledge what we have done, we are here today more to learn how to stretch

Along the way we also learned about

- the Interagency Regulatory Reinvention Forum.
- a source of agency people with experience in changing how we do business.
- and we invited the Office of the Chief Counsel and our Integrity Officer

We will use what we learn here today and the sources we have gleaned along the way when we design OL projects during tomorrow's workshop.

THE CONFERENCE PACKAGE

- T.O.C.
- Web pages, CRADAs [see the resource table] & Tech transfer options.
- DOJ laboratories

Together we have an opportunity to

- learn and
- to glimpse a future where ...

We hope to lighten our loads AND be more effective.